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Dr Long 24/7/85

- ln use

adopted:

7.

2 has the same problem

Presancture syika

may be elicited
by informal inquiries

०५

3.9.

3.3.

6.0.

4.8.

5.0

3.2.

one of 4: if

U.K. is lunch

A re-formulated

ASMP. For the an

4° storage acceptable?

out for reformulation?

for creamer pack only

formation having

supporting data

page 15 only done.

G005295

Review of the original formulation

3. Challenge the syng containing methyl propyl and butylparaben (after 37°/17h storage = 30°/2yr) with 15% opacina at room temp. If results satisfactory, get analysis done and submit another PL application. For the USA, more stability parameters will have to be set up to cover PET

4. Major Reformulation

4.1 Use the same bottles as in 2 but include

5% w/w EtOH and challenge with 1% opacina. If

this is satisfactory (and 1, 2 and 3 are not) then:

- a) Check acceptability of EtOH in chewing gum
b) Check syng acceptability of all other reagents
c) Put up more UK stability bottles for PL challenge
d) USA NDA

- 4.2 Repeat 4.1 with 2.5% w/v prepylene glycol.
4.3 Repeat 4.1 with 0.1% w/v phanet.

Submissions for 4.1, 4.2, 4.3 would probably need to be self-reporting

4.4 Pros and Cons of Propylene Glycol and Ethanol

Acceptable daily intake for 20kg subject	25mg/kg 500mg	Lower.
Acceptable conc in 20ml syng	2.5% w/v	
Antimicrobial activity	moderate inhibitory	→
Medical acceptability	known OK for Plaster	intensity OK
Stability of mixtures	✓	✓
Flavour preservative? Manufacture?	flavouring Plaster	12% Plaster
Volatility glass/PET	✓	✓
Facilitates manufacture to dissolve particles	✓	✓
Dosage	1.04g	0.8g
Q.P.	185-189	78
Taste test	satisfactory	burning

Mayer Reproduction - No data. fixed cost?

In addition to the in-use externalization problem there are other less-than-perfect properties of the 'string' - string development on storage

- Placenta per
- mit Placenta late (at 0.59, 1.1)
- placenta hydatidosa exscent by time cont

These aspects should be considered at placental

These aspects

1. if card is hard (complete 2/18/85)

5.1 Preservative

possible ^{3/2} E transition (physical processes)

0.175 hand

E Baykhus

Phenylethylamine

Pharynx

Brenn

Li₂ Sucro

Benzalkoniumchlorid

vasatikhem

Chlorobut

benzoc

Serbie

Pharynx

5.2 longc dft

1
Padua

HPMC

omit

Sat 30
C.F.

here

Flasas

Hemphill

Could be

09-10

3

- useful

CONF

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